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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/088,951	06/02/1998	MARTIN A CHEEVER	920010.535	2326

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/088,951	CHEEVER ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 9, 11 and 12 have been amended and are under consideration.

2. The text of sections of Title 35 US Code not found in this action can be found in a prior Office Action.

3. The rejection of claims 9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Carson et al (US 5,679,647, cited in a previous Office action) in view of Lau et al (US 6,080,409, cited in a previous Office action) is maintained for reasons of record.

Claim 9 is drawn to a method of eliciting or enhancing a T cell response to a human self tumor antigen comprising immunizing a human being with a composition consisting essentially of a protein or portion thereof with an amino acid sequence native to a non-human source, wherein the non-human protein or portion thereof has at least 80% amino acid sequence homology to the human self tumor antigen but is not identical in amino acid sequence to the human antigen, and wherein the human self tumor antigen is human prostatic acid phosphatase (PAP). Claim11 embodies the method of claim 9 wherein the composition further includes a pharmaceutically acceptable carrier or diluents. Claim 12 embodies the method of claim 9 or 11 wherein the composition further includes an adjuvant.

Carson et al teach a method for the induction of tumor associated antigen-specific cytotoxic T-lymphocytes (section III beginning on column 21, line 18 to column 30, line 32). Carson et al teach that T-lymphocyte tolerance to self-antigens in more effectively broken through co-immunization of the host with polynucleotide encoding self antigens and foreign antigens that resemble self antigens , and therefore to optimize the breakdown of T-lymphocyte tolerance to a tumor associated antigen in the host, the host will be preferentially immunized to express homologous and heterologous tumor associated antigens (column 29, lines 56-64). Carson et al teach tumor associated antigens from a species other than the host species (which are immunologically similar to the tumor associated antigens present on tumor cells in the host species) are heterologous tumor associated antigen mimics in addition to synthetically modified self-antigens which are homogeneous tumor associated antigen mimics (column 27, lines 6-13). Carson et al teach how to modify and select mimic antigens which stimulate T-lymphocyte

responses (column 26, lines 9-30). Carson et al teach that the method of the invention could be applied to generate CTL against tumor associated antigens on cells of the intact tumor as well as residual cancer cells (column 21, lines 34-41). Cason et al teach a method wherein the host is co-immunized using a vector encoding an immunostimulatory cytokine (claim 10), thus fulfilling the specific embodiment of claim 12 specifying and adjuvant. Carson et al teach that examples of tumor associated antigens are prostate specific transmembrane protein (column 21, lines 44-48). Carson et al do not teach prostatic acid phosphatase as a tumor associated antigen.
Laus et al teach that prostatic acid phosphatase is a tumor associated antigen (column 4, lines 11-13). Laus et al teach that there is no evidence in the literature that PAP by itself might serve as an inducer and target of CTL (column 6, line 66 to column 7, line 1). Thus, Laus et al teaches the negative limitation of claim 9 specify that the protein or portion thereof is not identical to human prostatic acid phosphatase. Laus et al teach a method of stimulating cytotoxic T-cell responses comprising inducing prostate carcinoma specific cytotoxic T-lymphocytes by prostatic acid phosphatase-GM-CSF pulsed antigen presenting cells (column 14, example 4).
Laus et al do not teach the administration of a protein having at least 80% identity.
It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the polynucleotide encoding prostatic acid phosphatase for the polynucleotide encoding prostate specific transmembrane protein in the method taught by Carson et al One of skill in the art would have been motivated to do so by the teachings of Carson et al regarding the necessity of immunizing with an tumor associated antigen mimic rather than the tumor associated antigen itself in order to avoid or break the induction of tolerance to the tumor antigen which is a self antigen; and further by the teachings of Laus regarding the expectation that the administration of PAP in an unaltered form would not result in anti-tumor immunity.
One of skill in the art would be motivated use a heterologous tumor associated antigen mimic or recombinantly produce a homologous tumor associated antigen mimic in order to elect or enhance a T cell response against PAP.

4. Applicant has amended claim 9 to recite a "composition consisting essentially of" rather than a composition "comprising" in order to disclaim methods having embodiments wherein both the foreign protein and the self protein are used I immunization in order to elicit or enhance

a T-cell response. Applicant states that the specification supports this limitation because it teaches that the use of the self-protein in the immunization protocol is optional. However, the specification lacks a definition for "consisting essentially of" which limit the scope of the composition to comprise only the foreign protein. The M.P.E.P. states that in this case, the claim should be interpreted as "comprising". Therefore, the rejection stands.

5. Applicant argues that Carsons reliance upon the teachings of Mamula (Journal of Immunology, 1994, Vol. 152, pp. 1453-1461) is misleading as Mamula et al do not teach that the breaking of T-cell tolerance can be carried out by immunization with the foreign protein alone. Applicant argues that it would not be obvious based on the teachings of Manula et al that administration of only the foreign protein would be sufficient to break tolerance as Mamula et al indicated that administration of the self-protein in addition to the foreign protein was necessary to break T-cell tolerance. This has been considered but not found persuasive., In considering at the specific details it is noted that Mamula et al is teaching breaking of tolerance to self U1 SNRP, which is a highly conserved intracellular protein not normally found as an extracellular protein. Mamula et al teach that co-immunization of mice with human and mouse snRNPs breaks T-cell tolerance to mouse snRNP. In this experimental system, the immune system within the mouse was not subjected to the self-snRNP until the co-immunization because snRNPs are intracellular proteins in normal mice. In the case of PAP, the immune systems of patients having prostate carcinoma would be subjected to the self PAP. It would not be necessary to co-immunize with the self-protein and the foreign protein because the self PAP protein is not an intracellular protein and its level is elevated in cancer patients. Administration of the foreign protein alone would be expected to duplicate co-administration of the foreign protein and the self protein in patient having elevated levels of PAP.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
8/23/2004

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER